



Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

January 11, 2000

Raymond C. Scheppach
The National Governors Association
444 N. Capitol Street
Washington, D.C. 20001-1512

Dear Mr. Scheppach:

The Food and Drug Administration (FDA) is soliciting comments on its proposed rule for "Suitability Determination for Donors of Human Cellular and Tissue-Based Products," ("proposed donor suitability rule"), published September 30, 1999, in the Federal Register (64 FR 52696). The proposed rule is part of the agency's proposed comprehensive new system of regulating human cellular and tissue-based products ("the proposed approach"), announced in February 1997. The proposed approach describes a rational and comprehensible framework under which tissue manufacturers could develop and market products without hindering innovation. At the same time, the proposed approach should provide physicians and patients with the assurance of safety that the public has come to expect from drugs, biologics, medical devices, and other products overseen by the FDA.

FDA has been soliciting comments since the announcement of the proposed approach in February 1997. FDA held a public meeting in March 1997 to solicit information and views from the interested public. The agency will publish the provisions of the proposed approach in three separate proposed rules for comment. The FDA intends to finalize the three proposed rules as one rule after consideration of all the comments from these rules. FDA first published the proposed rule for the "Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products" on May 14, 1998, in the Federal Register (63 FR 26744). The agency subsequently published the proposed donor suitability rule and requested comments within 90 days, although the agency intends to extend the comment period to accommodate a request from the industry. In the near future, the agency plans to publish a proposed rule to establish current good tissue practice for manufacturers of human cellular and tissue-based products.

With this letter, FDA seeks consultation from the States on the proposed donor suitability rule, and specifically on any preemption issues raised by the proposed rule. In considering preemption issues, the agency would appreciate your comment on: (1) the need for the proposed donor suitability determination rule to prevent communicable disease transmission through human cellular and tissue-based products; (2) alternatives that would limit the scope of such national requirements or otherwise

preserve State prerogatives and authority; (3) FDA's proposal not to preempt State laws on legislative consent for cornea transplants; (4) the proposed donor

suitability determination provisions, in particular provisions for directed donors of reproductive tissue; (5) the proposed exceptions from donor suitability testing and screening requirements; and (6) any other issues raised by this proposed rule possibly affecting State laws and authorities.

In addition to the Federal Register (64 FR 52696, September 30, 1999), the proposed donor suitability rule can be found at www.fda.gov/cber/rules/suitdonor.pdf or www.fda.gov/cber/rules/suitdonor.txt .

Please send written comments within 90 days of receipt of this letter to: Docket No. 97N-484S, Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Md. 20852.

If your organization has designated a contact person for this issue, please advise us. The agency's contact person at the Center for Biologics Evaluation and Research is Paula McKeever, who can be reached at 301-827-6210.

Sincerely,

Kathryn C. Zoon, Ph.D.
Director,
Center for Biologics Evaluation
and Research

cc:

State Attorneys General
State Health Commissioners